

## REMARKS

Pending in the application are claims 1 – 12 of which claims 1, 10, 11 and 12 are independent. Claims 1, 10, 11 and 12 have been amended. The following comments address all stated grounds of rejection and place the presently pending claims, as identified above, in condition for allowance.

### I. Summary of the Claimed Invention

In accordance with the present invention claimed in independent claim 1, the prosthesis includes a first tube of biologically compatible material, a polymer membrane positioned about the exterior surface of the first tube, and at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula. The membrane has a microstructure of nodes interconnected by fibrils effective to *facilitate bonding* of the support structure to the membrane and *inhibit delamination* of the support structure from the membrane

In accordance with the present invention claimed in independent claim 10, the prosthesis includes a first tube of biologically compatible material, a membrane of polymer material positioned about an exterior surface of the exterior surface of the first tube, and a plurality of spaced-apart rings placed about the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula. The membrane has a microstructure of nodes interconnected by fibrils effective to *facilitate bonding* of the rings to the membrane and *inhibit delamination* of the rings from the membrane.

In accordance with the present invention claimed in independent claim 11, the prosthesis includes an inner tube of polymer material, a membrane of polymer material positioned about the exterior surface of the inner tube, and at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially

spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula. The membrane has a microstructure of nodes interconnected by fibrils, the nodes being oriented at angle relative to the winding axis effective to *facilitate bonding* of the support structure to the membrane.

In accordance with the present invention claimed in independent claim 11, a method of making a prosthesis includes providing a first tube of biologically compatible material, positioning a membrane of polymer material about the exterior surface of the first tube, and winding at least one support structure along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the exterior surface that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula and the ridges being apart a distance effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging. The spaced apart distance is less than 1.5 times the outer diameter of the needle. The membrane has a microstructure of nodes interconnected by fibrils effective to *facilitate bonding* of the support structure to the membrane and *inhibit delamination* of the support structure from the membrane.

## II. Claim rejections under 35 U.S.C. §103

### Rejections of Independent Claim 1

The Office Action rejects claims 1-5 and 8-9 under 35 U.S.C. §103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5, 879, 587). The Office Action also rejects claims 6-7, which depend from independent claim 1, under 35 U.S.C. §103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5, 879, 587) in view of Campbell et al. (U.S. Patent No. 5,747,128). Applicants respectfully submit that pending claims 1-9 are not obvious.

As Examiner agrees, the '587 patent does not disclose having the membrane connected to the exterior of the tube, and then having the support structure helically wound around the membrane. The '587 patent discloses the support structure wound around the first tube, with the membrane secured on the top of the supporting structure.

Applicant owns '587 patent and described the problems of the '587 patent on page 1, lines 31-33 in the application of the present invention. With the structure of the '587 patent, the support structure can frequently delaminate from the underlying prosthesis during cannulization due to insufficient bonding of the support structure to the prosthesis. The present invention is provided to overcome the problems associated with '587 patent.

For this purpose, independent claim 1 provides an interface layer in the form of a membrane of polymer material between the exterior surface of the first tube and the support structure. The polymer membrane has a microstructure of nodes interconnected by fibrils effective to *facilitate bonding* of the support structure to the polymer membrane and *inhibit delamination* of the support structure from the membrane when the prosthesis is subject to cannulization.

The '587 patent does not disclose an interface membrane between the exterior surface of the first tube and the support structure. Furthermore, the '587 patent does not teach or suggest a membrane of a microstructure of nodes for *facilitating bonding* of the support structure to the polymer membrane and *inhibiting delamination* of the support structure from the membrane when the prosthesis is subject to cannulization.

Independent claim 1 is believed to be non-obvious and in position for allowance because the '587 patent fail to teach or suggest all of the claim limitations of claim 1. Independent claim 1 teaches a prosthesis with different structure than the '587 patent and thus achieves an enhanced effect.

The addition of dependent claims 2-5, 8-9, which depend from aforementioned claim 1, does not render the pending application obvious in light of the '587 patent. The addition of dependent claims 6-7, which teach the microstructure of the membrane and depend from aforementioned claim 1, does not render the pending application obvious in light of the '587 patent in view of the '128 patent.

In lieu of this, Applicants therefore submit that the Examiners 35 U.S.C. 103(a) rejection is moot, and dependent claims 1-9 are in position for allowance.

#### Rejections of Independent Claim 10

The Office Action rejects claim 10 under 35 U.S.C. §103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5, 879, 587) in view of Inoue (U.S. Patent No. 5,976,179). Applicants respectfully submit that pending claim 10 are not obvious in light of the '587 and '179 patents.

Independent claim 10 provides a membrane of polymer material between the exterior surface of a first tube and a plurality of rings. The polymer membrane has a microstructure of nodes interconnected by fibrils effective to *facilitate bonding* of the rings to the polymer membrane and *inhibit delamination* of the rings from the membrane when the prosthesis is subject to cannulization.

Although '587 patent and '179 patent indicate or disclose a ring or rings as a supporting structure in independent claim 1, neither of the patents teach or suggest a membrane of polymer material between the exterior surface of the first tube and a plurality of rings. In particular, the patents do not teach or suggest a polymer membrane of a microstructure of nodes for *facilitating bonding* of the support structure to the polymer membrane and *inhibiting delamination* of the rings from the membrane when the prosthesis is subject to cannulization

Independent claim 10 is believed to be non-obvious and in position for allowance because the cited patents fail to teach or suggest all of the claim limitations of independent claim 10.

Rejections of Independent Claim 11 and 12

The Office Action rejects claims 11 and 12 under 35 U.S.C. §103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5, 879, 587). Applicants respectfully submit that pending claims 11 and 12 are not obvious.

With respect to claim 11, the '587 patent does not disclose a membrane between exterior of an inner tube and a support structure. The '587 patent does not teach or suggest that the membrane has a microstructure of nodes that are being oriented at angle relative to the winding axis effective to *facilitate bonding* of the support structure to the membrane.

Independent claim 12 provides a method of making a prosthesis including the steps of positioning a membrane of polymer material about the exterior surface of the first tube, and winding at least one support structure along a winding axis about an exterior surface of the membrane. The '587 patent does not disclose a method of making a prosthesis by positioning a membrane between a first tube and a support structure. In particular, the '587 patent does not teach or suggest that the spaced apart distance of ridges is less than 1.5 times the outer diameter of the needle.

Applicants have determined not by a design choice but by due experiments that the spaced apart distance effective to inhibit needle plowing is a distance approximately less than 1.5 times the outer diameter of the needle.

Furthermore, the '587 patent does not teach or suggest a membrane of a microstructure of nodes for *facilitating bonding* of the support structure to the membrane and *inhibiting delamination* of the support structure from the membrane.

Independent claims 11 and 12 is believed to be non-obvious and in position for allowance because the '587 patent fails to teach or suggest all of the claim limitations of independent claims 11 and 12.

### **Conclusion**

In light of the aforementioned claim amendments, Applicants contend that each of the Examiners rejections have been adequately addressed and the pending application is in condition for allowance.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version With Markings To Show Changes Made"**. Should the Examiner feel that a telephone conference with Applicants' attorney would expedite prosecution of this application, the Examiner is urged to contact the Applicants' attorney at (617) 227-7400.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims**

Please amend claims 1, 10, 11 and 12 as follows:

1. (Amended) A prosthesis for surgical implantation to replace a segment of a blood vessel, the prosthesis comprising:
  - a first tube of biologically compatible material having an exterior surface,
  - a membrane of polymer material positioned about the exterior surface of the first tube, and
  - at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane and inhibit delamination of the support structure from the membrane.
  
10. (Amended) A prosthesis for surgical implantation to replace a segment of a blood vessel, the prosthesis comprising:
  - a first tube of biologically compatible material having an exterior surface,
  - a membrane of polymer material positioned about the exterior surface of the first tube, and
  - a plurality of spaced-apart rings placed about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the rings to the membrane and inhibit delamination of the rings from the membrane.

11. (Amended) A prosthesis comprising:

an inner tube of polymer material having an exterior surface,  
a membrane of polymer material positioned about the exterior surface of  
the inner tube, and

at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula, the membrane having a microstructure of nodes interconnected by fibrils, the nodes being oriented at angle relative to the winding axis effective to facilitate bonding of the support structure to the membrane.

12. (Amended) A method of making a prosthesis, the method comprising:

providing a first tube of biologically compatible material having an  
exterior surface,

positioning a membrane of polymer material about the exterior surface of  
the first tube, and

winding at least one support structure along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the exterior surface that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula and the ridges being apart a distance effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging, the spaced apart distance being less than 1.5 times the outer diameter of the needle, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane and inhibit delamination of the support structure from the membrane.